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K113774
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510(k) Summary

Date Prepared: December 19, 2011

1. **Owner's Name:** **PruGen, IP Holdings Inc.**
8714 E. Vista Bonita Drive
Scottsdale, AZ 85255

Contact Person: **Bhiku Patel, Ph.D.**
(T): 480-585-0122 ext. 3
(F): 480-393-5873
(E): bpatel@prugen.com

2. **Proprietary Name:** HPR™ Plus Emollient Foam
Common Name: Dressing, Wound & Burn, Hydrogel w/ Drug or Biologic
Classification Name: Dressing, Wound & Burn, Hydrogel w/ Drug or Biologic
(Product Code MGQ)

3. **Substantially Equivalent Device:**

PruGen IP Holdings, Inc. believes that HPR™ Plus Emollient Foam is substantially equivalent to the following currently marketed device: Hylatopic™ Plus Emollient Foam cleared under K093051.

4. **Device Description:**

HPR™ Plus Emollient Foam is a non-steroidal, non-sterile, off-white, low odor, fragrance free, topical aerosol foam. When HPR™ Plus Emollient Foam is dispensed, foam is formed. The propellant in the foam dissipates very quickly and the foam is then rubbed on the affected skin. The HPR™ Plus Emollient Foam when applied to diseased skin forms a protective barrier that helps to maintain a moist wound and skin environment. This device is presented as a prescription product that requires the physician to diagnosis of the disease state and prescribes the product.

5. **Intended Use of the Device:**

HPR™ Plus Emollient Foam is indicated to manage and relieve the burning, itching, and pain experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. HPR™ Plus Emollient Foam also helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

6. **Summary of Technical Characteristics of Device compared to Predicate Devices**

The predicate device referenced is a non-sterile foam that is applied topically to relieve the symptoms of various dermatoses. When HPR™ Plus Emollient Foam is dispensed, foam is formed. The propellant in the foam dissipates very quickly and the foam is then rubbed on the affected skin. The rubbed in product is equivalent to gel or cream.

7. Testing and Conclusions:

Functional and performance testing has been conducted to assess the safety and effectiveness of HPR™ Emollient Foam and all results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 9 2012

PruGen, IP Holdings Inc.
% Bhiku Patel, Ph.D.
8714 East Vista Bonita Drive
Scottsdale, Arizona 85255

Re: K113774
Trade/Device Name: HPR™ Plus Emollient Foam
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 24, 2012
Received: January 25, 2012

Dear Dr. Patel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Date: December 19, 2011

INDICATIONS FOR USE

Device Trade Name: HPR™ Plus Emollient Foam

510(k) number: K113774

Rx Only

FOR TOPICAL DERMATOLOGICAL USE ONLY

HPR™ Plus Emollient Foam is indicated to manage and relieve the burning, itching and pain associated with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis, and radiation dermatitis. HPR™ Plus Emollient Foam also helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Prescription Use __X____ (21 CFR 801 Subpart D)	Over-The-Counter _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113774